

## REMARKS

This amendment is in response to the Office Action, dated April 27, 2006, ("Office Action"). It is respectfully submitted that the application is in condition for allowance. Claims 1-14 and 19-33 were pending. Claim 14 was objected to and claims 1-14, and 19-33 were rejected. Claims 1-3, 5-9, 11-13, 19 and 24-26 have been amended; and claims 4, 14 and 31 have been canceled (claims 15-18 having previously been canceled). Following entry of the present amendment, claims 1-3, 5-13, 19-30 and 32-33 are pending. No new matter has been added. Allowance and reconsideration of the application in view of Applicant's amendment and the ensuing remarks are respectfully requested. Applicant reserves the right to pursue other aspects of the present invention in later filed applications.

Claims 1-3, 6-9 and 11-13 have been amended to insert a comma in various places.

Claim 5 has been amended to adjust the claim dependency.

Claims 8 and 13 have been amended to adjust the syntax.

Claims 1 and 19 have been amended such that the composition is used for the "treatment" of IBD.

Claims 1-2, 6, 19 and 24-26 have been amended to recite that the soluble fibre is "derived" from fruit of the *Musa* spp.

Claims 2 and 25 have been amended to recite that the aqueous solution is "decanted" from fruit of the *Musa* spp.

Claims 2, 8-9 and 25 have been amended to recite that the fruit is "fruit of the *Musa* spp."

Claims 1, 19 and 24 have been amended to recite that the soluble fiber is "substantially starch free." Support for this amendment may be found throughout the specification; for example, pages 6-7.

Claim 24 has been amended to indicate that IBD is treated by the claimed method. Support for this amendment may be found through the specification.

Examiner objected to claim 14 under 37 C.F.R. 1.75(c) as being of improper dependent form for failing to further limit the subject matter of the claim from which it depends. Applicant has canceled claim 14 and thus this objection is rendered moot.

Examiner rejected claims 1-2, 12-21, and 23 under 35 U.S.C. §101 as being directed to non-statutory subject matter for allegedly being drawn to a product of nature. With respect to canceled claim 14 and previously canceled claims 15-18, this rejection is rendered moot. With respect to claims 1-2, 12-13, 19-21, and 23, this rejection is respectfully traversed.

Patentable subject matter includes "nonnaturally occurring manufacture or composition of matter – a product of human ingenuity – having a distinctive name, character and use." Moreover, "the production of articles for use from raw materials prepared by giving to these material new forms, qualities, properties, or combinations whether by hand labor or by machinery is a "manufacture" under 35 U.S.C. §101." (Internal quotations omitted.) See MPEP §2105 (citing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)).

Applicant respectfully submits that claims 1-2, 12-13, 19-21, and 23 are not drawn to a product of nature. These claims, as amended, are drawn to extracted, substantially starch free soluble fiber. Applicant recognizes that the soluble fiber is derived from a product of nature (*i.e.*, from a fruit of the *Musa* spp.). However, the substantially starch free soluble fiber, by itself, does not exist in nature. Claims 1-2, 12-13, 19-21, and 23 are not drawn to the soluble fiber in its native state; these claims are drawn to extracted, substantially starch free soluble fiber which is a product of human intervention and not a product of nature. Thus, claims 1-2, 12-13, 19-21, and 23 are not drawn to a product of nature. In light of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §101.

Examiner rejected claims 1-14 and 19-23 under 35 U.S.C. §112, first paragraph, as not being enabling for a composition and a method for the prevention of Inflammatory Bowel Disease ("IBD"). Examiner affirmed that the specification is enabling for a composition and a method for treating IBD. With respect to canceled

claims 4 and 14, this rejection is rendered moot. With respect to claims 1-3, 5-13 and 19-23 this rejection is respectfully traversed. Claims 1 and 19 have been amended such that the composition is used for the "treatment" of IBD. Applicant respectfully submits that amended claims 1 and 19, and claims that depend therefrom are enabled by the specification. In light of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §112.

Examiner rejected Claims 1-14 and 19-33 under 35 U.S.C. §112, second paragraph, as being indefinite. Examiner found that the use of the term "derivable" rendered claims 1-2, 6, 19, 24-26, and any claim that depend therefrom, vague and indefinite. Also, the use of the term "decantable" was found to render claim 2 vague and indefinite. Further, Examiner found the term "fruit" as used in claims 2, 8-9, 25, and any claim that depend therefrom, rendered those claims vague and indefinite. With respect to canceled claims 4, 14 and 31, this rejection is rendered moot. With respect to claims 1-3, 5-13, 19-30 and 32-33 this rejection is respectfully traversed.

Claims 1-2, 6, 19 and 24-26 have been amended to recite that the soluble fibre is "derived" from fruit of the *Musa* spp. Claims 2 and 25 have been amended to recite that the aqueous solution is "decanted" from fruit of the *Musa* spp. Claims 2, 8-9, and 25 have been amended to recite that the fruit is "fruit of the *Musa* spp." Applicant respectfully submits that amended claims 1-2, 6, 8-9, 24-26, and claims that depend therefrom are not indefinite. In light of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §112.

Examiner rejected claims 1-14 and 19-33 under 35 U.S.C. §102(b) as anticipated or alternatively, under 35 U.S.C. §103(a) as being obvious over Fagbemi (Plant Foods for Human Nutrition 54:261-269, 1999).

Examiner found that Fagbemi teaches a composition obtained from *Musa* spp. and a method for obtaining it. Examiner found that the flour disclosed by Fagbemi is "produced from plantains which were peeled, sliced, blanched at 100°C (boiling), drying, milling and further drying the fruit." Examiner stated that the flour is intrinsically in the form of a powder and Fagbemi disclosed that the flour contains "crude fiber which would

intrinsically contain the soluble fiber instantly claimed." Examiner also found that Fagbemi teaches that the flour can be incorporated into food and beverage products.

Examiner asserted that even if the claimed extract composition is not identical to the composition identified by Fagbemi, the differences are slight because the Fagbemi composition is "likely to inherently possess the same characteristics of the claimed extract composition." Examiner also stated that "the inevitable ingestion of the food product taught by Fagbemi would intrinsically treat Inflammatory Bowel Disease with respect to preventing Inflammatory Bowel Disease." Examiner also found the "adjustment of particular conventional working conditions (e.g., adding a wash step using ethanol) is deemed merely a matter of judicious selection and routine optimization" for one skilled in the art and thus obvious. Examiner conceded that Fagbemi does not teach that the composition may be used to treat IBD. However, examiner found that the intended use set forth by the claims do not patentably distinguish the composition because such undisclosed use is inherent in the referenced composition.

With respect to canceled claims 4, 14 and 31, these rejections are rendered moot. With respect to claims 1-3, 5-13, 19-30 and 32-33, these rejections are respectfully traversed.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP §2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Furthermore, a reference cannot be relied upon as anticipatory to the extent that the scope of its disclosure does not reasonably suggest those aspects relied upon in the rejection. See *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); MPEP §2123.

Additionally, three basic criteria must be met to establish a *prima facie* case of obviousness: (1) "there must be some suggestion or motivation...to combine reference teachings," (2) "there must be a reasonable expectation of success," and (3) *the prior art references "must teach or suggest all the claim limitations."* MPEP §2142 (emphasis added). A reconstruction based on hindsight reasoning may be proper if it takes account only knowledge which was within the level of ordinary skill in the art at the time

of the claimed invention was made and does not include knowledge gleaned from applicant's disclosure. See *In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

New and unobvious uses of a known compound, based on an unknown property of the compound, may be patentable. See MPEP 2112.02 (citing *In re Hack*, 245 F.2d 246, 248 (CCPA 1957)).

When making a rejection based on inherency, an Examiner must provide rationale or evidence tending to show inherency. "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." See MPEP §2112(IV) (citing *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (emphasis in original). Further, "to establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" Id. (citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999)).

Applicant respectfully submits that Fagbemi does not anticipate Applicant's invention because Fagbemi does not teach the composition, the method of producing the composition, or the method of using the composition to treat IBD as required by Applicant's claims.

#### The Compositions Are Novel and Nonobvious

As to the composition claims, Fagbemi does not expressly or inherently describe each and every element as set forth in the claims. Fagbemi discloses flour that contains *crude* fiber whereas Applicant's claims encompass *substantially starch free soluble* fiber. Examiner asserted that the crude fiber disclosed by Fagbemi intrinsically contains soluble fiber. However, Examiner did not provide evidence that the crude fiber indeed contains soluble fiber or that it would be so recognized by persons of ordinary skill in the art. In fact, there is a difference between crude fiber and soluble fiber. Crude fiber may include *bran* and *skins* of vegetables. (See M. Downs, "Studies show some

natural alternatives relieve symptoms for irritable bowel syndrome," WebMD (2004), [www.webmd.com/content/Article/84/98248.htm](http://www.webmd.com/content/Article/84/98248.htm); Exhibit A.) Thus, there are differences between crude fiber and soluble fiber. This is an important distinction as Applicant has found that it is the soluble fiber that is effective in the treatment of IBD. Further, Applicant has found that it is undesirable to have high starch content in the soluble fibers. (See specification page 6.) While Fagbemi teaches boiling the fruit, which may remove some starch, the amount of starch removed may not be enough to produce a substantially starch free soluble fiber as claimed by Applicant's claims. Indeed, Applicant teaches the removal of substantially all the starch from the soluble fiber by treatment with starch degrading enzymes (see Specification pages 6-7).

Fagbemi also does not cause Applicant's claims to be obvious. Examiner asserted that it was a matter of judicious selection to adjust particular working conditions. Applicant respectfully disagrees with Examiner's position. Applicant found that it was the soluble fiber and more specifically, substantially starch free soluble fiber that imparted a therapeutic effect for subjects with IBD. This decision to extract the soluble fiber for use in treating IBD is based on Applicant's research and understanding of the bacteria found in the digestive tract. (See generally Specification; for example, page 3).

#### The Methods of Producing the Compositions Are Novel and Nonobvious

As to the method of producing the composition, Fagbemi does not teach or suggest each and every element of Applicant's claims. Fagbemi does not teach all of the steps that are set forth in Applicant's claims. Fagbemi does not teach any of the following: hydrolyzing the solution with starch digesting enzymes; precipitating and washing the material with ethanol and freeze drying or spray drying to produce a residue; reconstituting the freeze-dried or spray-dried residue, boiling and centrifuging. As such, it cannot be viewed that Fagbemi anticipates claims 1-3, 5-13, which require substantially starch free soluble fiber (which may be obtained using starch digesting enzymes) and/or one or more of the aforementioned steps.

Fagbemi does not render obvious the method of producing the composition. Fagbemi's teachings merely produced flour. There were no additional suggestion or

motivation to modify its flour to obtain a composition that comprises substantially starch free soluble fiber.

The Methods of Treating IBD Are Novel and Nonobvious

Fagbemi does not teach or suggest a method of treating IBD with a soluble fibre derived from fruit of *Musa* spp. Even assuming for a moment that Applicant's composition is not new, which Applicant in no way concedes, a new and unobvious use of the composition based on an unknown property is still patentable. Applicant has found that soluble fiber is effective in treating IBD. This finding was a discovery of an unknown property and thus the method of treating IBD using the soluble fiber is a new and unobvious use of the soluble fiber. Examiner asserted that IBD is inherently treated through the "inevitable ingestion of the food product taught by Fagbemi." However, Examiner did not provide evidence to show the inherency or that one skilled in the art will recognize that Fagbemi's composition will treat IBD. The fact that treatment of IBD *may* occur with Fagbemi's composition is not sufficient to establish inherency. Applicant has shown that it is the soluble fiber that is capable of treating IBD (see generally Specification and see Example 1). Applicant has also found that a substantially starch free soluble fiber is effective. Fagbemi's composition is not substantially starch free. Thus, it cannot be assumed that Fagbemi's composition will treat IBS.

In light of the foregoing remarks, Applicant respectfully requests reconsideration and withdrawal of these rejections under 35 U.S.C. §102(b) and §103(a).

All of the claims remaining in the application are now believed to be allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

**Applicant also requests that Examiner note the change in the Attorney docket number. The new attorney docket number for this matter is 81886-2.**

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (213) 633-6869.

Respectfully submitted,

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Appendix:

Exhibit A: M. Downs, "Studies show some natural alternatives relieve symptoms for irritable bowel syndrome," WebMD (2004), [www.webmd.com/content/Article/84/98248.htm](http://www.webmd.com/content/Article/84/98248.htm).

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Original page:  
<http://www.webmd.com/content/Article/84/98248.htm>



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## Natural Alternatives for IBS

### Studies show some natural alternatives relieve symptoms for irritable bowel syndrome.

By Martin Downs  
WebMD Feature

Reviewed By Brunilda Nazario, MD

Many people turn to natural treatments to relieve symptoms because there is no one treatment for irritable bowel syndrome (IBS) that works for everyone, and because scientists have yet to pinpoint the exact cause of the condition. Studies of some natural alternatives have had promising results, but none are proven.

Irritable bowel syndrome is not a disease. As the name implies, it is a syndrome — a group of symptoms that fit a pattern. The main symptoms of IBS are problematic bowel movements, gut pain, and bloating. Some people who suffer from IBS have constipation, others have diarrhea, and some have both.

Before it was called IBS, the syndrome was usually known as "spastic colon." There is nothing physically wrong with the intestines of people with IBS, but the contractions that move food through the digestive tract may be disturbed. With IBS the nerves and the muscles in the bowel are extra sensitive. It's also thought that IBS sufferers may be particularly sensitive to the rumbling and burbling that goes on in the bowel during digestion. What you eat may play a role, too.

Christine Frissora, MD, a gastroenterologist at New York's Weill Medical College of Cornell University, says that before she writes a prescription to treat people who have the condition, she encourages IBS patients to try lifestyle changes. "They have to stop smoking, they have sleep, they have to eat properly, they have to exercise," she says.

### You Feel What You Eat

When it comes to eating properly, some people find that cutting certain foods out of their diet helps. What you eat obviously has different effects on your bowel. Fluids also help stool pass regularly. "I always recommend water and soluble fiber — meaning fibers that are gentle on the GI tract, such as oatmeal, berries, lentils, and split peas," Frissora says.

"Dietary modification, I always tell patients, needs to be individualized," says Philip Schoenfeld, MD, a gastroenterologist at the University of Michigan and spokesman for the American College of Gastroenterology. "Each patient tends to be a little bit different in terms of food or drinks that tend to spur their irritable bowel syndrome symptoms," he says.

For example, if your worst IBS symptom is pain caused by bloating, eating lots of beans and leafy greens wouldn't be best for you, because they cause gas. But if you primarily have trouble with constipation, then adding fiber to your diet may help. Frissora points out that there is a difference between soluble and "crude" fiber. Crude fiber includes bran and the skins of vegetables such as eggplant and bell pepper. These things can be irritants and don't help.

Other commonly reported triggers for IBS symptoms include:

- Dairy products such as milk and cheese

- Fatty foods such as French fries
- Alcohol
- Caffeine found in coffee and some sodas
- Chocolate
- Carbonated drinks such as soda

### Probiotics: In With the Good

Some people may begin to have IBS symptoms in the wake of an intestinal infection such as *Salmonella*. It's not that the infection causes the IBS, but "somehow that seems to affect the normal motility of their small intestine and their colon," Schoenfeld says.

It's possible that an infection changes the types and amounts of bacteria normally present in your intestines, upsetting digestion. Probiotics are natural supplements that promote the growth of healthy bacteria that aid digestion. "Instead of killing bacteria, you're putting something in that will allow healthy bacteria to flourish," Frissora says.

Taking probiotics may help IBS sufferers who can pinpoint the start of their problems on a recent case of food poisoning or gastroenteritis. "That may be where the probiotics are more effective," she says.

Two examples of probiotics are *Saccharomyces boulardii* and *Lactobacillus acidophilus*. *S. boulardii* is a yeast culture, sold in capsules by the brand name Florastor. *L. acidophilus* is a bacterium that can be found in yogurt, and is also available as a supplement in pill or powder form. These probiotics have been widely studied as treatments for various digestive problems, but there have been few studies done specifically for IBS.

### Acupuncture

Several studies have looked at the use of acupuncture as an alternative way to ease IBS symptoms, and the results have been generally promising. Although it's still not a proven treatment, Frissora says she thinks it is worth trying when all else fails.

Acupuncture probably doesn't fix diarrhea or constipation, but it may help with discomfort caused by gas. "If the patient has more of the pain-bloat IBS, they might respond better to acupuncture because that would mediate the pain," Frissora says.

If IBS pain is caused by a special sensitivity of the enteric nervous system – the nerves that wire the brain to the gut – acupuncture could perhaps alter the signals the brain reads as painful sensations.

"I think that a lot of the success of acupuncture depends upon who's doing it and how much experience they have with IBS," she says. She recommends checking with your insurance company to find out if there is an acupuncturist on the plan.

### Fiber Supplements

In a study published in the *American Journal of Gastroenterology*, Schoenfeld looked all the studies done to date on several natural fiber supplements, or stool "bulking agents," used in treating IBS. These included:

- Wheat bran
- Corn fiber
- Calcium polycarbophil (brand name Fibercon)
- Psyllium

In general, the studies showed that fiber supplements helped with constipation. They were not, however, much

better for other IBS symptoms compared with a placebo.

### The Mind-Gut Connection

IBS is not caused by stress, but many people say it aggravates their symptoms. Exercise is one of the best ways to relieve stress.

Alternative practices such as yoga and tai chi are known to help people cope with stress, but they haven't been studied as way of managing IBS. Nevertheless, Frissora says they can't hurt. "I think that any exercise is good for IBS," she says. "I tell patients, I don't care what kind of exercise you want to do." Walking, running, and swimming are good, too.

What's more, Schoenfeld says, "If you exercise regularly, the frequency of your bowel movements will increase. If you can get people with irritable bowel syndrome to have a more regular pattern of moving their bowels, that usually provides some relief for their IBS symptoms."

Behavioral therapy is sometimes considered for people with IBS, although the syndrome isn't merely a product of one's mind. A number of studies have shown that many kinds of behavioral therapy can help IBS symptoms, including:

- Relaxation therapy
- Hypnosis therapy
- Biofeedback
- Cognitive therapy
- Psychotherapy

The studies that Schoenfeld reviewed for the *American Journal of Gastroenterology* showed that these things worked, but he could not say for certain that they are proven beyond any doubt because of problems with how the various studies were done.

Frissora says she thinks hypnotherapy is best suited to people whose IBS is worsened in anxiety-inducing situations such as public speaking or flying on a plane. She says she thinks psychotherapy is most helpful for people who feel that their IBS symptoms are related to an emotional trauma.

March 29, 2004.

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SOURCES: Philip Schoenfeld, MD, assistant professor, University of Michigan School of Medicine; spokesman, American College of Gastroenterology. Christine Frissora, MD, assistant professor, Weill Medical College of Cornell University, New York. *American Journal of Gastroenterology*, 2002. *Comprehensive Therapy*, 2002. National Digestive Diseases Information Clearinghouse web site. National Library of Medicine web site.

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